

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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FOREST LABORATORIES, LLC, FOREST	)	
LABORATORIES HOLDINGS, LTD., MERCK	)	
KGaA and MERCK PATENT GESELLSCHAFT	)	
MIT BESCHRÄNKTER HAFTUNG,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 15-272 (GMS)
	)	<b>CONSOLIDATED</b>
ACCORD HEALTHCARE INC.,	)	
	)	
Defendant.	)	

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FOREST LABORATORIES, LLC, FOREST	)	
LABORATORIES HOLDINGS, LTD., MERCK	)	
KGaA and MERCK PATENT GESELLSCHAFT	)	
MIT BESCHRÄNKTER HAFTUNG,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 15-277 (GMS)
	)	
INVAGEN PHARMACEUTICALS INC.,	)	
	)	
Defendant.	)	

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FOREST LABORATORIES, LLC, FOREST	)	
LABORATORIES HOLDINGS, LTD., MERCK	)	
KGaA and MERCK PATENT GESELLSCHAFT	)	
MIT BESCHRÄNKTER HAFTUNG,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 15-1078 (GMS)
	)	
INVAGEN PHARMACEUTICALS INC.,	)	
	)	
Defendant.	)	

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**STIPULATION AND [PROPOSED] ORDER**

The Court, upon the consent and request of Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Merck KGaA and Merck Patent Gesellschaft Mit Beschränkter

Haftung (collectively, “Plaintiffs”), and Defendant InvaGen Pharmaceuticals Inc. (“InvaGen”), hereby acknowledges the following Stipulation and issues the following Order.

**STIPULATION**

1. This Court has subject matter jurisdiction over the above-captioned patent infringement actions (the “Actions”) and personal jurisdiction over Plaintiffs and InvaGen for purposes of the Actions. Venue is proper in this Court as to Plaintiffs and InvaGen for purposes of the Actions.

2. In the Actions, Plaintiffs have asserted claims against InvaGen for infringement of U.S. Patent Nos. 7,834,020 (“the ‘020 Patent”), 8,193,195 (“the ‘195 Patent”), 8,236,804 (“the ‘804 Patent”), and 8,673,921 (“the ‘921 Patent”) (collectively the “Patents in Suit”) in connection with InvaGen’s submission of Abbreviated New Drug Application (“ANDA”) 208200 directed to generic vilazodone hydrochloride 10, 20 and 40 milligram tablet products to the U.S. Food and Drug Administration (“FDA”).

3. In response to Plaintiffs’ claims of patent infringement, InvaGen has alleged certain defenses and counterclaims, including that the Patents in Suit are not infringed and/or are invalid. To date, no final judgment has been entered by this Court regarding Plaintiffs’ claims or InvaGen’s defenses or counterclaims.

4. For purposes of the Action, InvaGen admits that submission of ANDA 208200 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, and/or sale of the generic vilazodone hydrochloride 10, 20 and 40 milligram tablet products within the United States before the expiration of the Patents in Suit was a technical act of infringement of the Patents in Suit under 35 U.S.C. § 271(e)(2)(A).

5. By this Stipulation and Order, the Parties agree that all other claims, defenses, counterclaims set forth in the pleadings in the Action, including allegations and averments contained therein, should be dismissed, without prejudice.

### **ORDER**

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Plaintiffs and InvaGen, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA No. 208200 was a technical act of infringement of the Patents in Suit under 35 U.S.C. § 271(e)(2)(A). No decision in the Action has been obtained by either party regarding the validity of the Patents in Suit and/or whether any commercial making, using, selling, or offering to sell within the United States, or importing into the United States, of the generic products described by ANDA No. 208200 would infringe those patents.

2. All other claims, defenses, and counterclaims set forth in Plaintiffs' and InvaGen's pleadings against each other in the Action, including the allegations and averments contained therein, are hereby dismissed, without prejudice.

3. Absent a license or other authorization by Plaintiffs or as otherwise permitted under 35 U.S.C. § 271(e)(1), InvaGen, its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the generic vilazodone hydrochloride 10, 20 and 40 milligram tablet products that are the subject of ANDA 208200 during the life of the Patents in Suit, including any extensions and pediatric exclusivities unless and until all of the claims of the Patents in Suit are found

invalid or unenforceable by a court decision from which no appeal has been or can be taken excluding any petition for a writ of certiorari or other proceedings before the United States Supreme Court.

4. Plaintiffs and InvaGen each expressly waive any right to appeal or otherwise move for relief from this Stipulation And Order.

5. This Court retains jurisdiction over Plaintiffs and InvaGen for purposes of enforcing this Stipulation And Order.

6. This Stipulation And Order shall finally resolve the Action between Plaintiffs and InvaGen.

7. Nothing herein prohibits or is intended to prohibit InvaGen from maintaining a "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. § 314.94(a)(12) with respect to any of the Patents in Suit.

8. The Clerk of the Court is directed to enter this Stipulation And Order in the above-captioned Action forthwith.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Maryellen Noreika*

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CAESAR RIVISE, PC

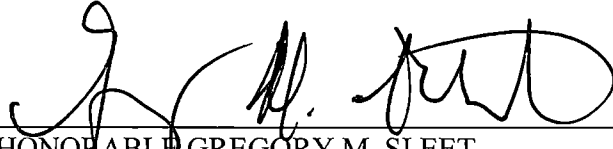
*/s/ R. Touhey Myer*

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*Attorneys for Defendant InvaGen  
Pharmaceuticals Inc.*

SO ORDERED this 24<sup>th</sup> day of October 2017



HONORABLE GREGORY M. SLEET  
UNITED STATES DISTRICT JUDGE